

REMARKS

As a preliminary matter, the undersigned thanks the Examiner for the courtesy of the informal teleconference conducted on 06/19/2006. The undersigned respectfully reminds the Examiner of the offer that was made to contact the undersigned to address any questions or concerns that the Examiner may have prior to generation of the next Action on the merits. Given the age of this Application, Applicants sincerely appreciate all efforts that the Examiner can make to expedite prosecution of this case.

As stated during the informal teleconference, Applicants believe the newly presented claims to be allowable over the art of record.

SUPPORT FOR PRESENTATION OF NEW CLAIMS:

Claims **48** and **61** (corresponding in scope to cancelled claims **1** and **22** as originally presented, respectively) are supported by the specification and claims as originally filed.

Applicants' specification at page 10, lines 12-17 discloses the term "unsaponifiable materials" to mean "compositions that comprise at least 6% by weight of total organic materials that are unsaponifiable and at least 10% by weight of organic materials that are saponifiable [...] includ[ing] compositions containing from 6-90% by weight of organics of unsaponifiable materials and 10-94% by weight of saponifiable materials". Accordingly, no new matter has been introduced in this regard.

Applicants' specification at page 13, line 28 thru page 14, line 1 explains that "products from the hydrolysis reaction of organic material that produce unsaponifiables comprise[...] polar hydrophilic salts (saponifiables) [...] and] non-polar, lipophilic materials (unsaponifiables)". Accordingly, no new matter has been introduced in this regard.

Applicants' respectfully request that the Examiner note that the presentation of new claims **48** and **61** further delineate and clarify the novel disclosure and non-obvious teaching of Applicants' specification; specifically, that an original organic starting material is subjected to an *in situ*

hydrolysis reaction to produce polar hydrophilic salts as a product of the formulation reaction itself without requiring mixing or blending with externally supplied non-polar, lipophilic materials as disclosed in the prior art. As previously discussed with the Examiner, the *in situ* production of polar hydrophilic salts in the formulation composition is a key differentiator of Applicants' technology from that taught or otherwise suggested in the prior art.

"*In situ*" is the Latin word for "in original position or place". See Merriam-Webster Dictionary online, <http://www.m-w.com/dictionary/in%20situ>

Main Entry: **in si-tu**

Pronunciation: (")in-'sl-(")tū, -'si-, -(")tyū also -'sE-, -(")chū

Function: adverb or adjective

Etymology: Latin, in position

: in the natural or original position or place

See also Answers.com, <http://www.answers.com/in%20situ>, defining *in situ* as "in the original or natural place or site".

While the Examiner will note that nowhere in Applicants' Application as originally filed does the phrase "*in situ*" appear, skilled artisans are aware that "*in situ*" is a common designation for describing reactions wherein the resulting products are left in the original place, such as the products of the alkaline hydrolysis reaction of the present invention – where the polar hydrophilic salts and the non-polar unsaponifiables are products of an original organic starting material which are produced "in place" and left "in place" after the reaction takes place. See Applicants' specification at page 8, lines 14-18: "It has been found that the application of hydrolysis to materials, particularly naturally derived matters, with a high unsaponifiables fraction (e.g., at least 6% by total weight of the material) in combination with a saponifiable fraction produces a Hydrolysate with properties that are significantly different from those products resulting from [...] conventional saponification" (describing an *in situ* hydrolysis reaction of a pre-reaction combination of unsaponifiable fraction and saponifiable fraction of original starting material in which the subsequent reaction products are produced "in place" and left "in place").

The distinction between Applicants' instant invention and the prior art is further described in the Background of Invention at page 3, line 28 thru page 4, line 5: "There are basically two distinct

types of [conventional saponification] processes. In a first method, oils and fats are boiled in an open kettle with caustic alkali solutions, bringing about saponification gradually until all of the fats and oils are completely saponified"; "In a second method [...] fatty acids and alkali are brought together in proper proportions for complete saponification in a mixing valve or other device which brings them in intimate contact". (*emphasis added*) At page 8, lines 12-14: "The very objective of [conventional] saponification processes is to increase the water-solubility and surfactant activity of naturally occurring materials". At page 8, lines 19-24: "The resulting products from the practice of [Applicants'] invention are substantive, water resistant, prevent unwanted absorption of a carried active ingredient by the applied surface, exhibit a unique surfactant functionality, and are not foaming agents with water. Some unexpected uses for the resulting Hydrolysates have been found to be as an emollient and/or an alternative natural carrying agent for topical application of cosmetics, pharmaceuticals, and bioactive agents, particularly to the skin of subjects".

Although the phrase "*in situ*" does not appear in the specification as originally filed, persons skilled in the art of chemical synthesis understand the process of subjecting reactants (*i.e.*, precursor products) to a chemical reaction in order to yield reaction product material that is produced "in place" and left "in place" (as opposed to producing a formulation via mixing, blending or other processes to introduce externally supplied ingredients and/or subsequently segregating the reaction products). See 37 CFR §1.132 Affidavits of Robert Kleiman and David Ashley as attached.

New claims **51, 52, 64 and 65** have been presented with support from the application as originally filed. Specifically, the specification discloses on page 12, lines 5-7 that "compositions of matter comprising waxes, oils, and/or fats (lipids) containing at least 6% by weight unsaponifiable ingredients and at least 10% by weight saponifiable ingredients are subjected to an alkaline hydrolysis reaction". Accordingly, "at least 20%" does not disclose new matter, since at least 20% is included within the scope of "at least 6%".

The Examiner has acknowledged Applicants' withdrawal of claims **14-21** and **35-47**. Claims **1-13** and **22-34** stand rejected and have been cancelled. After entry of the preceding amendments, newly presented claims **48-73** are pending in the instant Application and allowance of these claims is respectfully requested.

35 USC § 102(b)

Claims 1-13 and 22-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Koulbanis *et al.* US 4,324,802. Notwithstanding that claims 1-13 and 22-34 have been cancelled, to the extent that Koulbanis may be cited against Applicants' newly presented claims 48-73, Applicants present the following for the Examiner's consideration:

The Examiner cites "example 8, Mg Lanolate and 9, La lauryl sulfate, as polar hydrophilic salts mixed with non-polar unsaponifiables, of example E and K; respectively" as evidence that Koulbanis anticipates the claimed invention. Applicants disagree with this assertion. The present invention discloses a composition for topical application to the skin, comprising non-polar unsaponifiables and polar hydrophilic salts produced as *in situ* products of hydrolysis of a saponifiable fraction of original organic material that comprises at least 10% unsaponifiable material prior to hydrolysis.

Koulbanis does not teach Applicants' invention. Rather, Koulbanis teaches separation of unsaponifiables from the salts and addition of the separated unsaponifiables to other organic material. See Koulbanis at col. 2, lines 14-24. Accordingly, Koulbanis does not teach non-polar unsaponifiables in combination with polar hydrophilic salts that are *in situ* products of the hydrolysis reaction of original organic starting material.

The Examiner asserts that "no patentable weight is given to how the processing was done; however, 40% non-saponifiable components are present ([Koulbanis at] col.2, lines 40-44) before processing and refinement according to known procedures ([Koulbanis at] col. 2 lines 20-24)" and "[t]hus, Koulbanis anticipates the instant claimed compositions".

It is important for the Applicants to point out for the Examiner's consideration that Applicants have limited the subject matter of their claims as drawn to only polar hydrophilic salts which are *in situ* products of the hydrolysis of an organic starting material comprising at least 10 percent unsaponifiable material or long-chain carbon material prior to hydrolysis. Koulbanis does not disclose *in situ* Hydrolysates in conjunction with non-polar unsaponifiables of original organic starting materials, regardless of the initial percentage concentration of unsaponifiable materials.

Claims **1-13** and **22-34** stand rejected under 35 U.S.C. § 102(b) as being anticipated by Moy US 5,928,659. Notwithstanding that claims **1-13** and **22-34** have been cancelled, to the extent that Moy may be cited against Applicants' newly presented claims **48-73**, Applicants present the following for the Examiner's consideration:

The Examiner cites that the Moy reference at "the last paragraph of col. 2 and col 3, top for the instant method claims to providing substantive benefits". Applicants are affirmatively unaware as to where in the cited paragraph, or anywhere in the remainder of the Moy reference, the elements of the present invention are disclosed; specifically, a composition for topical application to the skin comprising, non-polar unsaponifiables and polar hydrophilic salts which are *in situ* products of hydrolysis of a saponifiable fraction of original organic material.

The Examiner goes on to state that "[n]o patentable weight is given to how the processing was done"; however, Applicants have affirmatively disclosed non-conventional, novel, and non-obvious formulations warranting consideration of the question as to how the novel materials may be otherwise produced utilizing conventional methods. Since, skilled artisans will not be able to produce a formulation in accordance with Applicants' invention with any existing known method, the non-conventional (*i.e.*, novel) method disclosed and taught by Applicants should be given weight and consideration with respect to patentability. Certainly, this should be the case given the stricter requirements for a rejection under 35 U.S.C. § 102(b).

Claims **1-3**, **6**, **7**, **10-13**, **22-24**, **27**, **28** and **31-34** stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dreger US 2,240,365. Notwithstanding that claims **1-3**, **6**, **7**, **10-13**, **22-24**, **27**, **28** and **31-34** have been cancelled, to the extent that Dreger may be cited against Applicants' newly presented claims **48-73**, Applicants present the following for the Examiner's consideration:

Since all of Applicants' claims are drawn to the use of polar hydrophilic salts resulting from *in situ* hydrolysis of original organic starting material comprising at least 10 weight percent of unsaponifiable material or long-chain carbon organic material prior to hydrolysis, the Dreger reference may not properly be used to formulate a rejection under U.S.C. § 102(b) – inasmuch as Dreger fails to at least disclose polar hydrophilic salts as *in situ* products of hydrolysis.

35 USC § 103(a)

Claims 1-13 and 22-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koulbanis *et al.* US 4,324,802 in view of Moy US 5,928,659. Notwithstanding that claims 1-13 and 22-34 have been cancelled, to the extent that Dreger may be cited against Applicants' newly presented claims 48-73, Applicants present the following for the Examiner's consideration:

Applicants respectfully disagree with the proposed combination of Koulbanis *et al.* (US 4,324,802) and Moy (US 5,928,659). Applicants further submit that a *prima facie* case of obviousness has not been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP 2143. Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner proposes that Koulbanis "provides the instant composition, but is not explicit as to the presence of 18 carbon materials as part of the starting materials". Applicants respectfully disagree. Nowhere does Koulbanis disclose, teach or otherwise suggest a composition that comprises non-polar unsaponifiables of an original starting material in conjunction with polar hydrophilic salts, where the polar hydrophilic salts are *in situ* products of hydrolysis of the original starting material. In fact, Koulbanis discloses the separation of unsaponifiables from the salts and addition of externally supplied unsaponifiables to other material (Koulbanis col. 2, lines 14-17). See 37 CFR §1.132 affidavits of Robert Kleiman and David Ashley.

The Examiner then goes on to propose that Moy "shows (col.3, lines 44-53) that avocado oil has palmitic and longer chain fatty acids, with, further, the refined products include sterols (col.3; lines 52-61)". Applicants respectfully disagree. Nowhere does Moy disclose, teach or otherwise describe a composition that comprises non-polar unsaponifiables of an original starting material, in conjunction with polar hydrophilic salts, where the polar hydrophilic salts are *in situ* products of hydrolysis of the original starting material, as recited in Applicants' newly presented claims.

In fact, the section of Moy cited by the Examiner (col. 3 lines 52-61) teaches away from the claimed invention by teaching **the exact opposite** proposition – **removal** of the saponifiable fraction after hydrolysis – followed by **mixing** and **blending** with other oils. See 37 CFR §1.132 affidavits of Robert Kleiman and David Ashley.

The Examiner further proposes that “no patentable weight [should be] given to how the processing was done”. It is important, however, for the Examiner to consider that Applicants’ have detrimentally limited the subject matter of their claims as drawn to only the polar hydrophilic salts which are *in situ* products of the hydrolysis of original organic starting material comprising at least 10 percent of unsaponifiable material and/or long carbon chain organics prior to hydrolysis. For the Examiner to suggest that these substantial limitations should not be given “patentable weight” seems unreasonable. Applicants would not have included these limitations unless they were deemed relevant to define and enable the instant invention over the art of record. Accordingly, it would be important for the Examiner to consider that no combination of Koulbanis and/or Moy discloses or claims a hydrolysis process for producing *in situ* polar hydrophilic salts.

Accordingly, Applicants’ submit that there is no motivation or suggestion to be found in Koulbanis and/or Moy, nor in the knowledge generally available to one of ordinary skill in the art, to modify the cited references with any other reference of record to practice the invention of Applicants’ claims as newly presented. Because there is no motivation or suggestion to combine Koulbanis in view of Moy with any other reference to practice Applicants’ invention, there can be no reasonable expectation of success. Where no motivation to combine can be found, any expectation of success concerning the proposed combination may only be regarded as unreasonable at best. Accordingly, Applicants’ newly presented claims should not be rejected under § 103(a). See, for example, *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186 (Fed. Cir. 2003) (There must be some teaching, suggestion, or motivation to combine references.); *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313 (Fed. Cir. 2002) (The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence.) (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)); *Carella v. Starlight Archery*, 804 F.2d 135 (Fed. Cir. 1986) (Obviousness cannot be established by combining teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting a combination.); *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) (The fact that the prior art could be modified so as to

produce the claimed invention is not a basis for an obviousness rejection, unless the prior art suggested the desirability of the modification.); and *Ex parte Walker*, 135 USPQ 195 (BOPA 1961) (A combination of teachings must be proposed and the art should contain some suggestion of the desirability of making the proposed combination.)

"With respect to core factual findings in a determination of patentability, [the Examiner] cannot simply reach conclusions based on [his/her] own understanding or experience – or on [his/her] assessment of what would be basic knowledge or common sense. Rather [the Examiner] must point to some concrete evidence in the record in support of these findings." *In Re Zurko*, 258 F.3d 1379 (2001). Accordingly, Applicants' pending claims may not properly be considered as obvious under § 103(a) in view of Koulbanis and Moy.

CONCLUSION

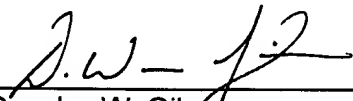
The remaining cited references (if any) have been reviewed and are not believed to affect the patentability of the claims as amended. Newly presented claims **48-73** are pending in the Application. Allowance of all pending claims **48-73** is earnestly requested.

No amendment made herein was related to the statutory requirements of patentability unless expressly stated; rather any amendment not so identified may be considered as directed *inter alia* to clarification of the structure and/or function of the invention and Applicants' best mode for practicing the same. Additionally, no amendment made herein was presented for the purpose of narrowing the scope of any claim, unless Applicants have argued that such amendment was made to distinguish over a particular reference or combination of references. Furthermore, no election to pursue a particular line of argument was made herein at the expense of precluding or otherwise impeding Applicants from raising alternative lines of argument later during prosecution. Applicants' failure to affirmatively assert specific arguments is not intended to be construed as an admission to any particular point raised by the Examiner.

Should the Examiner have any questions regarding this Response and Amendment or feel that a telephone call to the undersigned would be helpful to advance prosecution of this matter, the Examiner is invited to call the undersigned at the number given below.

Respectfully submitted,
ATTORNEY FOR APPLICANTS

Date: 11/03/2006



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Pronunciation: (") in-'sI-(") tū, -'si-, -(") tyū also
-'sE-, -(") chū

Function: *adverb or adjective*

Etymology: Latin, in position

: in the natural or original position or place <an *in situ*
cancer confined to the breast duct>

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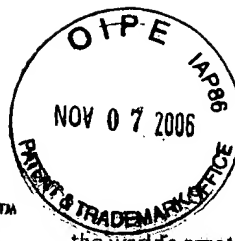
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The *adverb* [in situ](#) has one meaning:

Meaning #1: in the original or natural place or site

Synonym: [in place](#)

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